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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,428	12/18/2001	Stephen Griffin	1001.1545101	6502
28075	7590	04/21/2004		
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420				
			EXAMINER FOREMAN, JONATHAN M	
			ART UNIT 3736	PAPER NUMBER 13

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/025,428

Applicant(s)

GRIFFIN ET AL. *ed*

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/3/04 has been entered.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 – 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In regards to claims 1 – 39, Applicant has amended the independent claims to include: “a core shaft” and “a polymeric member disposed on and attached to...the shaft”. Applicant has disclosed a polymeric member (36, 38) being disposed on and attached to a shaft (22) (Col. 5, lines 4 – 14). However, this shaft is a hypotube through which the core shaft (26) passes (Page 4, line 19 – 21). There is no disclosure of disposing on or attaching the polymeric member to the core shaft.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 – 12, 16 – 28, 32 – 35 and 37 – 39 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,059,815 to Lee et al.

In regards to claims 1 – 12, 16 – 28 and 32, Lee et al. discloses applicant's claimed invention including: a core shaft (53) having a proximal portion and a distal portion; a tubular polymeric member (52) comprising a shape memory polymer disposed on and attached to the distal portion of the shaft (Col. 8, lines 44 - 53), the polymeric member having a first flexibility at a first temperature and a second flexibility at a second temperature, wherein the first temperature is less than the second temperature and the first flexibility is less than the second flexibility (Col. 4, lines 47 – 59); and a heat source (56) on the distal portion of the shaft, the heat source being in thermal communication with the polymeric member (Col. 8, lines 44 – 47), where activation of the heat source causes the polymeric member to rise from the first temperature to the second temperature (Col. 8, lines 44 – 49). The first temperature is below the glass transition temperature and the second temperature is above the glass transition temperature (Col. 8, lines 47 – 53). The distal portion of the shaft has a tip portion including a coiled wire resistive heating element (Col. 8, line 44). The functional statement set forth in a “whereby” clause does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. *In re Mason*, 244, F.2d 733, 114 USPQ 127 (CCPA 1957).

In reference to claims 33 – 35 and 37 - 39, Lee et al. discloses a method including: providing a guide wire including a distal portion and a core shaft (53), a distal polymeric member (52) attached to the core shaft having a glass transition temperature (Col. 8, lines 44 - 53), and a heat source (56) comprising a resistive heating element in thermal communication with the polymeric member (Col.

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8, lines 44 – 47; Col. 8, lines 58 - 62); and changing the flexibility of the distal portion of the guide wire by activating or deactivating the heat source by supplying or removing electrical energy to the heating element and heating the polymeric member above the glass transition temperature (Col. 8, lines 47 - 53). Activating the heat source inherently increases the flexibility of the distal portion of the guide wire while deactivating the heat source decreases the flexibility of the distal portion in that heating of the polymeric member softens the member. The guide wire is navigated through the patient's vasculature to a target site (Col. 5, lines 10 – 12).

### *Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,059,815 to Lee et al.

In regards to claim 36, it is well known in the art to advance a device over a guide wire to a target site. It would have been obvious to one having ordinary skill in the art to advance a device such as a catheter employing any of a variety of sensors over the guide wire as disclosed by Lee et al. to a target site to monitor the target site after the depositing of material as taught by Lee et al. at the target site (Col. 5, lines 10 – 18).

### *Conclusion*

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,800,500 to Spelman et al.

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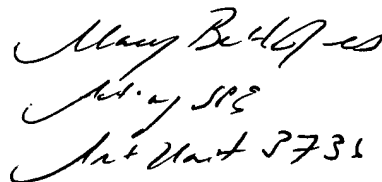
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



JMLF  
April 18, 2004



Mary Beth Jones  
Mary SP2  
Art Unit 3736